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SECTION IV

510(k) SUMMARY

As required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew ULTRABRAID™ II Suture

Date Prepared: May 14, 2010

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Christina Flores

Regulatory Affairs Specialist II

Phone: (508) 261-3705

FAX: (508) 261-3620

C. Device Name

Trade Name:	ULTRABRAID II Suture
Common Name:	Non-absorbable Surgical Suture
Classification Name:	Polyethylene Non-absorbable Surgical Suture

D. Predicate Devices

The Smith & Nephew ULTRABRAID II suture is substantially equivalent in Intended Use and fundamental scientific technology to the legally marketed Smith & Nephew ULTRABRAID suture cleared via K041216.

E. Description of Device

The Smith & Nephew ULTRABRAID II is a non-absorbable, sterile, synthetic surgical suture composed of either white UHMW polyethylene and/or blue UHMW polyethylene. The proposed suture is in a braided configuration and will be offered in sizes 2-0 through 2 meeting USP requirements except for slight variation in the diameter as described in the U.S.P Monogram for synthetic nonabsorbable surgical suture. ULTRABRAID II suture will be

provided either pre-loaded onto suture anchors or sold separately, with or without attached needles. When used with various anchoring implants in orthopedic procedures, the suture secures and holds the re-attached tendon to the bone.

F. Intended Use

Indications for Use:

The Smith & Nephew ULTRABRAID™ II Suture is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

G. Comparison of Technological Characteristics

The Smith & Nephew ULTRABRAID II suture is substantially equivalent in intended use, technological characteristics, and is as safe and effective as its currently marketed predicate devices, the Smith & Nephew ULTRABRAID suture (K041216). The differences which include a minor change to braid configuration and a material change in the blue fiber from a polypropylene pigmented monofilament to blue polyethelene, do not raise new questions of safety or efficacy.

H. Summary Performance Data

Non-clinical testing that included knot break strength, needle attachment strength, and diameter properties were performed and the results demonstrate that the Smith & Nephew ULTRABRAID II suture is substantially equivalent to the predicate ULTRABRAID suture, cleared via K041216. Biocompatibility testing was conducted and the results meet the biocompatibility requirements of ISO 10993-1 for Implant Device, Bone/Tissue contact, Permanent contact. The testing also demonstrates that the differences in the new device and the predicate devices do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Christina Flores
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

APR - 8 2011

Re: K101377
Trade/Device Name: Smith & Nephew ULTRABRID™ II Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: March 31, 2011
Received: April 1, 2011

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101377

Device Name: Smith & Nephew ULTRABRAID™ II Suture

Indications For Use:

The Smith & Nephew ULTRABRAID™ II Suture is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krum for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101377